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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,442	04/13/2000	TIMO LAAKSO	003300-634	7079

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EXAMINER

DEWITTY, ROBERT M

ART UNIT PAPER NUMBER

1616

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,442

Applicant(s)

LAAKSO ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-44 are pending in the instant application. Claims 43 and 44 are withdrawn from consideration as being directed to a non-elected invention.

Acknowledgement is made of Applicant's RCE filed 11/8/02.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendments "...wherein the biodegradable polymer can be dissolved in an organic solvent ..." was not supported by the original specification. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tice et al. (U.S. Pat. No. 5,407,609), further in view of Ekman et al. (U.S. Pat. No. 4,822,535).

Tice is drawn to methods for microencapsulating an agent to form a microencapsulated product. In preparation, a polymer is first dissolved in a solvent. The solvent can be selected from a variety of common organic solvents. The active substances is then added to the solvent containing the polymer.

Ekman relates to the production of small spherical polymer particles. Ekman teaches that when using an organic solvent as a phase when producing droplets, organic solvents currently used in the art are not very desirable environmentally or health wise. Ekman teaches that polyethylene glycol is preferably used as a polymer in the continuous phase of the invention (col. 3, lines 40-44). Whereas water is removed during the process to form the particles, in use only a small amount of water need be removed in order to form the particles.

Motivation to utilize propylene glycol as the continuous phase in the invention of Tice would have arisen because, as taught by Ekman, polyethylene glycol is a preferred phase in comparison to standard organic solvents when making microparticles (see Tice).

Response to Arguments

2. Applicant's arguments have been fully considered but they are not persuasive.

Applicant asserts that the polymers of the claimed invention being only soluble in an organic solvent is an inherent teaching. Applicant has relied on In re Robertson, 49 USPQ2D 1949 (1999) as teaching to establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing

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described in the reference, and would be so recognized by persons of ordinary skill”.

However, in finding that there was no inherency, the Court relied upon the holding in In re Oelrich “Inherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”.

In the instant case, Applicant has relied upon the teachings at page 1, line 34 to page 6, line 7 which disclose preparative techniques and release properties of polymers that are not soluble in water. However, the examiner would like to point out that these teachings were relegated to the prior art, and not necessarily the instant invention. The instant invention, at page 11 lines 8-14, teaches the polymer can be dissolved in an organic solvent and is slightly soluble in the outer phase (poly(ethylene glycol)/aqueous phase. The instant specification does not make clear that the missing limitation (only dissolvable in organic solvent) is present, and one with ordinary skill in the art would not so recognize the missing limitation as inherent. The missing limitation is at most a probability or possibility and is not sufficient to establish inherency, and support the amendment of claims 1 and 24 to include the limitation.

Regarding the rejection under 35 U.S.C. 103(a), Applicant asserts that the amended claims are sufficient to overcome the teachings of the prior art. The examiner acknowledges that Ekman’s method of making particles is based upon removal of water (distillation, osmosis, filtration), and Tice’s method of making particles involves extraction of the solvent, however Ekman teaches that water is removed only minimally. Furthermore, Ekman is relied upon to teach the benefits of using a polymer such as

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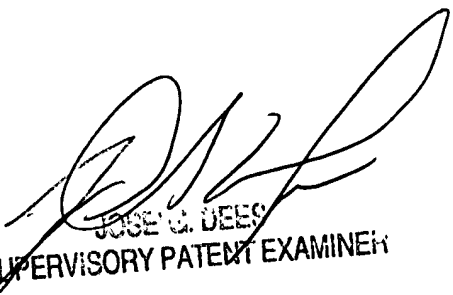
polyethylene glycol in making the particles, namely decrease in harm to the environment, and to handlers of the aqueous solvent. Thus, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
January 23, 2003


JOSE C. DEES
SUPERVISORY PATENT EXAMINER
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